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APPLICATION NO. ATTORNEY DOCKET NO. CONFIRMATION NO. FILING DATE FIRST NAMED INVENTOR 10/714,168 11/14/2003 GUA002 2255 Carlos A. Guanche **EXAMINER** 35830 7590 09/16/2005 LAWRENCE N. GINSBERG DAWSON, GLENN K 21 SAN ANTONIO ART UNIT PAPER NUMBER NEWPORT BEACH, CA 92660-9112

3731

DATE MAILED: 09/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

		Ann	ligation No	Annline n4(n)	<u> </u>	
Office Action Summary			lication No.	Applicant(s)		
			714,168 		GUANCHE, CARLOS A.	
			miner	Art Unit		
	The MAILING DATE of this commun		in K. Dawson	3731	ddsooo	
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1)[Responsive to communication(s) file	d on				
•		b)⊠ This actio	n is non-final.			
,	,—					
۵,۰	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims						
4)⊠ Claim(s) <u>1-40</u> is/are pending in the application.						
-	4a) Of the above claim(s) is/are withdrawn from consideration.					
	5) Claim(s) 12-40 is/are allowed.					
· <u> </u>	5)⊠ Claim(s) <u>1-11</u> is/are rejected.					
·	Claim(s) is/are objected to.					
Application Papers						
9)⊠ The specification is objected to by the Examiner.						
10)⊠ The drawing(s) filed on <u>14 November 2003</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 						
2)	t(s) e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (P nation Disclosure Statement(s) (PTO-1449 or r No(s)/Mail Date <u>11-14-2003</u> .		Paper No	Summary (PTO-413) s)/Mail Date Informal Patent Application (PT 	[*] O-152)	

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Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the specification does not provide antecedent basis for the loop having a diameter of about 5mm.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3 and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Lenkauskas-4624672.

Lenkauskas discloses a support coil having a proximal portion 22', an intermediate portion 10 and a distal portion 20,22. The distal portion has 3 coils and ends in a straight terminal portion 22.

Claims 1-3 and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Landers-2621917.

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Landers discloses a coil support having a proximal portion 10, an intermediate portion 12 and a distal portion 7 having 8 coils and a terminal straight portion 8.

Claims 1-3 and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Rowan-2973805.

Rowan discloses a support having a proximal portion 20, an intermediate portion 10 and a distal portion 22 having 3 coils and a straight terminal portion 24.

Claims 1-3 and 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Hussein, et al.-5810836.

Hussein discloses a coil support having a proximal, intermediate and distal portion. Depending on the embodiment the terminal portion can be 27 or either end as shown in fig. 8D.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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Claims 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenkauskas-'672 in view of Taylor 5279564 and Giannuzzi-4668144.

Lenkauskas discloses the invention as claimed with the exception of the material and dimensions of the spring coil. Taylor discloses that it was known to manufacture a coil out of nitinol and Giannuzzi discloses the manufacture of a coil out of plastic. It would have been obvious to have made the coil support of Lenkauskas out of the claimed materials, as these have been shown to be well-known coil/spring materials due to their resiliency.

As no criticality was given for the wire dimensions, they are considered nothing more than obvious design choices, as the prior art would perform equally as well as the applicant's wire.

M.P.E.P 2144-

IV. CHANGES IN SIZE, SHAPE, OR SEQUENCE OF ADDING INGREDIENTS

A. Changes in Size/Proportion

In re Rose, 220 F.2d 459, 105 USPQ 237 (CCPA 1955) (Claims directed to a lumber package "of appreciable size and weight requiring handling by a lift truck" where held unpatentable over prior art lumber packages which could be lifted by hand because limitations relating to the size of the package were not sufficient to patentably distinguish over the prior art.); In re Rinehart, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976) ("mere scaling up of a prior art process capable of being scaled up, if such were the case, would not establish patentability in a claim to an old process so scaled." 531 F.2d at 1053, 189 USPQ at 148.). In Gardner v. TEC Systems, Inc., 725 F.2d 1338,

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220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

Claims 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Landers-'917 in view of Taylor 5279564 and Giannuzzi-4668144.

Landers discloses the invention as claimed with the exception of the material and dimensions of the spring coil. Taylor discloses that it was known to manufacture a coil out of nitinol and Giannuzzi discloses the manufacture of a coil out of plastic. It would have been obvious to have made the coil support of Landers out of the claimed materials, as these have been shown to be well-known coil/spring materials due to their resiliency.

As no criticality was given for the wire dimensions, they are considered nothing more than obvious design choices, as the prior art would perform equally as well as the applicant's wire.

Claims 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rowan-805 in view of Taylor 5279564 and Giannuzzi-4668144.

Rowan discloses the invention as claimed with the exception of the material and dimensions of the spring coil. Taylor discloses that it was known to manufacture a coil out of nitinol and Giannuzzi discloses the manufacture of a coil out of plastic. It would have been obvious to have made the coil support of Rowan out of the claimed

materials, as these have been shown to be well-known coil/spring materials due to their resiliency.

As no criticality was given for the wire dimensions, they are considered nothing more than obvious design choices, as the prior art would perform equally as well as the applicant's wire.

Claims 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hussein, et al.-'836 in view of Taylor 5279564 and Giannuzzi-4668144.

Hussein discloses the invention as claimed with the exception of the material and dimensions of the spring coil. Taylor discloses that it was known to manufacture a coil out of nitinol and Giannuzzi discloses the manufacture of a coil out of plastic. It would have been obvious to have made the coil support of Hussein out of the claimed materials, as these have been shown to be well-known coil/spring materials due to their resiliency.

Allowable Subject Matter

Claims 12-40 are allowed.

The following is a statement of reasons for the indication of allowable subject matter: the prior art does not disclose or fairly suggest a cannula delivery and support system including a support coil having a proximal clip portion, an intermediate portion and a distal portion with a plurality of revolutions, a terminal portion of which has less curvature than previous portions, a sheath for containing the coil, a trocar having an outer surface smaller than the inner surface of the sheath and having a smaller

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diameter than the revolutions of the coil to maintain the revolutions about the lower portion of the trocar; the lower portion being atraumatic; or a method of delivering and supporting a cannula in a cavity including the steps of making an incision, utilizing the incision to insert the above cannula delivery and support system, pulling the trocar out of the sheath, inverting the trocar and reinserting it into the sheath and using it as a plunger to push the coil towards the lower end of the sheath so that the terminal portion anchors to the cavity lining; removing the sheath leaving the coil within the cavity, inserting a cannula into the cavity within the revolutions and placing the clip portion about a sideport of the cannula.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Glenn K. Dawson whose telephone number is 571-272-4694. The examiner can normally be reached on M-Th 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Glenn K Dawson Primary Examiner Art Unit 3731

Gkd 14 September 2005